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**SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Application Number	10/040,010
Filing Date	January 4, 2002
First Named Inventor	Thomas M. Mills
Group Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	M0351-267875
Express Mail Certificate	EV 032 110 529 US

Sheet	1	of	2
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	1/15/04
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 4

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Application Number 10/040,010
Filing Date January 4, 2002
First Named Inventor Mills, T. M. et al.
Group Art Unit Unassigned
Examiner Name Unassigned
Attorney Docket Number M0351-267875

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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
SAO	1	4,127,118		Latorre, Alvaro	11-28-78	
	2	4,801,587		Voss, Gene et al.	01-31-89	
	3	4,968,679		Bodo Junge, Wuppertal et al.	11-06-90	
	4	5,059,603		Rubin, David	10-22-91	
	5	5,242,391		Place, V. A. et al.	09-07-93	
	6	5,256,652		El-Rashidy, Ragab	10-26-93	
	7	5,888,534		El-Rashidy, Ragab et al.	03-30-99	
	8	5,945,117		El-Rashidy, Ragab et al.	08-31-99	
	9	5,981,563		Lowrey, Fred	11-09-99	
	10	6,007,824		Duckett, M. J. et al.	12-28-99	
	11	6,051,594		Lowrey, Fred	04-18-00	
	12	6,087,362		El-Rashidy, Ragab	07-11-00	
	13	6,093,181		Place, V. A. et al.	07-25-00	
	14	6,100,270		Campbell, S. F.	08-08-00	
	15	6,100,286		Lowrey, Fred	08-08-00	
	16	6,124,337		Lowrey, Fred	09-26-00	
	17	6,166,061		Lowrey, Fred	12-26-00	
	18	6,239,117 B1		Christ, G. J. et al.	05-29-01	
	19	6,266,560 B1		Zhang, L. et al.	07-24-01	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ² (if known)				
SAO	20	BG	103246A (abstract translation)		Yoshitomi Pharmaceu- tical Industries Ltd.	05-31-00		✓
	21	EP	0633023A1		Eli Lilly & Co.	01-11-95		✓
	22	JP	7048254 (abstract translation)		Eli Lilly & Co.	02-21-95		✓
	23	WO	98/06433 (abstract translation)		Yoshitomi Pharmaceu- tical Industries Ltd.	02-19-98		✓
	24	WO	00/33845 (abstract translation)		Yoshitomi Pharmaceu- tical Industries Ltd.	06-15-00		✓
Examiner Signature		Date Considered				4/15/04		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known

Application Number	10/040,010
Filing Date	January 4, 2002
First Named Inventor	Mills, T. M. et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	M0351-267875

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SAD	25	AMANO, M., et al., Phosphorylation and Activation of Myosin by Rho-associated Kinase (Rho-kinase), <i>J. Biol. Chem.</i> , 271 , 20246-20249, 1996	✓
	26	ANDERSSON, K.E., Pharmacology of Penile Erection, <i>Pharmacol. Rev.</i> , 53 , 417-450, September 2001	✓
	27	APENSTROM, P., Effectors for the RHO GTPases, <i>Curr. Opin. Cell. Biol.</i> , 11 , 95-102, 1999	✓
	28	BERMAN, J.R., et al., Anatomy and Physiology of Female Sexual Function and Dysfunction, <i>Eur. Urology</i> 38 , 20-29, 2000	✓
	29	BIVALACQUA, T.J., et al., Adenoviral gene transfer of endothelial nitric oxide synthase (eNOS) to the penis improves age-related erectile dysfunction in the rat, <i>Int. J. Impotence Res.</i> , 12 , S8-S17, September 2000	✓
	30	BURNETT, A.L., Role of Nitric Oxide in the Physiology of Erection, <i>Biol. Reprod.</i> , 52 , 485-489, 1995	✓
	31	CHAMPION, H.C., et al., Gene transfer of endothelial nitric oxide synthase to the penis augments erectile responses in the aged rat, <i>Proc. Natl. Acad. Sci., USA</i> , 96 , 11648-11652, 1999	✓
	32	CHITALEY, K., et al., Antagonism of Rho-kinase stimulates rat penile erection via nitric oxide-independent pathway, <i>Nature Med.</i> , 7 , 119-122, January 2001	✓
	33	CHITALEY, K., et al., RhoA/Rho-kinase: a novel player in the regulation of penile erection, <i>Int'l J. of Impotence Research</i> , 13 , 67-72, April 2001	✓
	34	CHITALEY, K., et al., Decreased penile erection in DOCA-salt and stroke prone-spontaneously hypertensive rats, <i>Int'l J. of Impotence Research</i> , 13 , Suppl 5, S16-S20, December 2001	✓
	35	CHRIST, G.J., et al., The application of gene therapy to the treatment of erectile dysfunction, <i>Int. J. Impotence Res.</i> , 10 , 111-112, 1998	✓
	36	CHRIST, G. J., et al., Intracorporal injection of <i>hSlo</i> cDNA in rats produces physiologically relevant alterations in penile function, <i>Am. J. Physiol.</i> , 275 , H600-608, 1998	✓
	37	DAI, Y., et al., Receptor-specific influence of endothelin-1 in the erectile response of the rat, <i>Am. J. Physiol. Regulatory Integrative Compl. Physiol.</i> , 279 , R25-R30, July 2000	✓
	38	DiSALVO, J., et al., Vanadate-Induced Contraction of Smooth Muscle and Enhanced Protein Tyrosine Phosphorylation, <i>Arch. Biochem. Biophys.</i> , 304 , 386-391, 1993	✓
	39	DUCKERS, H.J., et al., Heme oxygenase-1 protects against vascular constriction and proliferation, <i>Nature Med.</i> , 7 , 693-698, June 2001	✓
	40	FENG, et al., Rho-associated Kinase of Chicken Gizzard Smooth Muscle, <i>J. Biol Chem.</i> , 274 , 3744-3752, 1999	✓
	41	GARBAN, H., et al., Cloning of Rat and Human Inducible Penile Nitric Oxide Synthase. Application for Gene Therapy of Erectile Dysfunction, <i>Biol. Reprod.</i> , 56 , 954-963, 1997	✓
SAD	42	ISHIZAKI, T., et al., Pharmacological Properties of Y-27632, a Specific	✓

SAD 1/15/04

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

Complete if Known

Application Number	10/040,010
Filing Date	January 4, 2002
First Named Inventor	Mills, T. M. et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	M0351-267875

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390		Inhibitor of Rho-associated Kinases, <i>Mol. Pharmacol.</i> , 57 , 976-983, May 2000	
	43	JAROW, I.P., et al., Clinical Efficacy of Sildenafil Citrate Based on Etiology and Response to Prior Treatment <i>J. Urology</i> 162 , 722-725, 1999	✓
	44	KIMURA, K., et al., Regulation of Myosin Phosphatase by Rho and Rho-Associated Kinase (Rho-Kinase), <i>Science</i> , 273 , 245-248, 1997	✓
	45	KUREISHI, Y., et al., Rho-associated Kinase Directly Induces Smooth Muscle Contraction through Myosin Light Chain Phosphorylation, <i>J. Biol. Chem.</i> , 272 , 12257-12260, 1997	✓
	46	LOWRY, O.H., et al., Protein Measurement with the Folin Phenol Reagent, <i>J. Biol. Chem.</i> , 193 , 265-275, 1951	✓
	47	MILLS, T., et al., Androgen Maintenance of Erectile Function in the Rat Penis, <i>Biol. Reprod.</i> , 46 , 342-348, 1992	✓
	48	MILLS, T., et al., Effects of Castration and Androgen Replacement on the Hemodynamics of Penile Erection in the Rat, <i>Biol. Reprod.</i> , 51 , 234-238, 1994	✓
	49	MILLS, T., et al., Androgenic Maintenance of the Erectile Response in the Rat, <i>Steroids</i> , 64 , 605-609, 1999	✓
	50	MILLS, T., et al., Androgenic Maintenance of Inflow and Veno-Occlusion during Erection in the Rat, <i>Biol. Reprod.</i> , 59 , 1413-1418, 1998	✓
	51	MILLS, T., et al., The Effect of an Inhibitor of Rho Kinase on the Erectile Response, <i>Int'l J. of Impotence Research</i> , Suppl 3, Abstract A1, September 2000	✓
	52	MILLS, T., et al., Inhibition of the Rho Kinase Pathway Leads to Penile Erection, <i>9th World Meeting on Impotence Research</i> , Perth Australia, Abstract P6, Nov. 26-30, 2000	✓
	53	MILLS, T., et al., Vasoconstrictors in erectile physiology, <i>Int'l J. of Impotence Research</i> , 13 , Suppl 5, S29-S34, December 2001	✓
	54	MILLS, T., et al., Effect of Rho-kinase inhibition on vasoconstriction in the penile circulation, <i>J. Appl. Physiol.</i> , 91 , 1269-1273, September 2001	✓
	55	MILLS, T., New Biochemical Pathway May Control Erection, <i>TheScientificWorld</i> , 1 , 184-185, May 2001	✓
	56	MOODY, J.A., et al., Effects of Long-Term Oral Administration of L-Arginine on the Rat Erectile Response, <i>J. Urology</i> , 158 , 942-947, 1997	✓
	57	OKAMURA, T., et al., Monkey corpus cavernosum relaxation mediated by NO and other relaxing factor derived from nerves, <i>Am J. Physiol.</i> , 274 , H1075-H1081, 1998	✓
	58	PFITZER, G., et al., Involvement of small GTPases in the regulation of smooth muscle contraction, <i>Acta Physiol. Scand.</i> , 164 , 449-456, 1998	✓
	59	REES, R. W., et al., Y-27632, an inhibitor of Rho-kinase, antagonizes noradrenergic contraction in the rabbit and human penile corpus cavernosum, <i>British J. of Pharmacology</i> , 133 , 455, June 2001	✓
	60	REES, R. W., et al., Human and rabbit cavernosal smooth muscle cells express Rho-kinase, <i>Int'l J. of Impotence Research</i> , 14 , 1-7, February 2002	✓
590	61	REILLY, C.M., et al., Androgens Modulate the α -Adrenergic Responsiveness of Vascular Smooth Muscle in the Corpus Cavernosum, <i>J.</i>	✓

590 1/13/04

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Sheet 4 of 4

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First Named Inventor	Mills, T. M. et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	M0351-267875

SAQ			of Andrology, 1, 26-31, 1997	
	62		REILLY, C.M., et al., Androgenic Regulation of NO Availability in Rat Penile Erection, <i>J. Andrology</i> , 18 , 110-115, 1997	✓
	63		REILLY, C.M., et al., Androgenic Maintenance of the Rat Erectile Response Via a Non-Nitric-Oxide-Dependent Pathway, <i>J. Andrology</i> , 18 , 588-594, 1997	✓
	64		RIDLEY, A., RHO: theme and variations, <i>Curr. Biol.</i> , 6 , 1256-1264, 1996	✓
	65		SAHAI, E., et al., RhoA effector mutants reveal distinct effector pathways for cytoskeletal reorganization, SRF activation and transformation, <i>EMBO J.</i> , 17 , 1350-1361, 1998	✓
	66		SAUZEAU, V., et al., Cyclic GMP-dependent Protein Kinase Signaling Pathway Inhibits RhoA-induced Ca ²⁺ Sensitization of Contraction in Vascular Smooth Muscle, <i>J. Biol. Chem.</i> , 275 , 21722-21729, July 2000	✓
	67		SAWADA, N., et al., cGMP-Dependent Protein Kinase Phosphorylates and Inactivates RhoA, <i>Biochem. Biophys. Res. Comm.</i> , 280 , 798-805, January 26, 2001	✓
	68		SCHOTT, E., et al., Expression of a recombinant preproendothelin-1 gene in arteries stimulates vascular contractility, <i>Am. J. Physiol.</i> , 272 , H2385-H2393, 1997	✓
	69		SOMLYO, A.P., et al., From pharmacomechanical coupling to G-proteins and myosin phosphatase, <i>Acta Physiol. Scand.</i> , 164 , 437-448, 1998	✓
	70		SOMLYO, et al., Signal transduction by G-proteins, Rho-kinase and protein phosphatase to smooth muscle and non-muscle myosin II, <i>J. Physiol.</i> , 522 , 177-185, January 2000	✓
	71		TRAISH, A., et al., Role of alpha adrenergic receptors in erectile function, <i>Int. J. Impot. Res.</i> , 12 , Suppl. 1, S48-63, March 2000	✓
	72		UEHATA, M., et al., Calcium sensitization of smooth muscle mediated by a Rho-associated protein kinase in hypertension, <i>Nature</i> , 389 , 990-994, 1997	✓
	73		VIRAG R., Indications and Early Results of Sildenafil (VIAGRA) in Erectile Dysfunction, <i>Urology</i> 54 , 1073-77, 1999	✓
	74		WEBER, et al., Enhanced Relaxation to the Rho-Kinase Inhibitor Y-27632 in Mesenteric Arteries from Mineralocorticoid Hypertensive Rats, <i>Pharmacology</i> , 63 , 129-133, October 2001	✓
	75		WINGARD, C. J., et al., Recovery of Penile Erection by Inhibition of Rho-Kinase in a Castrate Rat Model of Erectile Dysfunction, <i>Int'l J. of Impotence Research</i> , 13 , Suppl 5, Abstract 1, December 2001	✓
SAQ	76		WINGARD, C. J., et al., Erection and NO override the vasoconstrictive effect of alpha-adrenergic stimulation in the rat penile vasculature, <i>Int'l J. of Impotence Research</i> , 13 , 212-220, August 2001	✓
Examiner Signature	SAQ		Date Considered	1/15/04

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